IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
HARRISONBURG DIVISION

KATHLEEN HIGGINS, *Individually and as a personal representative of the estate of Francis Krivicich,*	)	
Plaintiff,	)	**Civil Action No.: 5:07cv00054**
v.	)	
FOREST LABORATORIES, et al.,	)	**By: Hon. Michael F. Urbanski United States District Judge**
Defendants.	)	

MEMORANDUM OPINION

Pending before the court are several motions, including three summary judgment motions filed by defendant, Forest Laboratories, Inc. ("Forest Labs"). The court addresses herein the most recent of these motions for summary judgment. Dkt. No. 144. For the reasons that follow, the court will grant the motion, rending all other pending motions moot.

I.

This is a failure to warn case regarding a prescription drug. Specifically, plaintiff Kathleen Higgins ("Higgins"), individually and as the personal representative of the estate of Francis Krivicich ("Krivicich"), brought this negligence and breach of warranty[1] action pursuant to the diversity jurisdiction of the federal courts after Krivicich, her husband, committed suicide while taking Lexapro. Forest Labs is the manufacturer of Lexapro, a selective serotonin reuptake inhibitor ("SSRI") antidepressant drug. Higgins asserts that Forest Labs failed to provide an adequate warning that Lexapro causes a new or increased risk of suicide among members of a certain at-risk

[1] Higgins originally labeled the second count in her compliant as a strict liability claim, but the court permitted her to amend that count. See infra note 4.

subpopulation, particularly during a change in dosage. That is, Higgins argues that Lexapro can actually cause some people to commit suicide who otherwise would not have done so.

During the six months prior to his suicide, Krivicich received mental health treatment from Dr. Francis Andres, a board certified psychiatrist. Dr. Andres originally prescribed Krivicich Lexapro on February 28, 2004. On March 22, 2004, the United States Food and Drug Administration ("FDA") issued a Public Health Advisory asking antidepressant manufacturers to change warning labels to recommend close observation of adult and pediatric patients treated with SSRI antidepressants for the emergence of suicidality. See March 22, 2004, FDA Public Health Advisory, Dkt. No. 90-9, at 2. The FDA specifically noted that it had not concluded that SSRIs cause worsening depression or suicidality. Id. Nevertheless, the FDA advised health care providers to carefully monitor patients at the beginning of drug therapy or when either increasing or decreasing dosages. Id. Finally, the warning recommended that prescribers should instruct patients, their families, and their caregivers to be alert for the emergence of suicidality. Id. at 3. A significant amount of press coverage, both in mainstream media outlets (e.g., CBS News, the Associated Press, the New York Times, the Washington Post) and in medical publications (e.g., the New England Journal of Medicine, the Journal of the American Medical Association) followed this advisory. See Aff. in Supp. of Mot. for Summ. J., Dkt. No. 146 (noting these publications). On July 10, 2004, Dr. Andres wrote Krivicich an additional Lexapro prescription. Krivicich saw another psychiatrist, Dr. Brian Doyle, on July 16, 2004, who continued him on Lexapro and a short acting antidepressant, Klonopin. Krivicich took his own life nine days later, on July 25, 2004.

One of Higgins proffered expert witnesses, Dr. Michael Hamrell, Ph.D., gave the opinion that as early as 2001 Forest Labs should have provided a warning for Lexapro along the following lines:

> Lexapro may increase the risk compared to placebo of suicidal thinking and behavior (suicidality). Anyone considering the use of

> Lexapro must balance this risk with the clinical need. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on Lexapro therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber.

Hamrell Expert Report, Dkt. No. 88-1, at 3.[2] Additionally, Higgins alleges that Forest Labs "did nothing to actually call [the March FDA Public Health Advisory] to the attention of practicing physicians, much less to patients or their families." Am. Compl. (Third), Dkt. No. 136, at ¶ 15. Indeed, Higgins asserts that Forest Labs "told [its] sales people that they were *NOT* to proactively discuss any such side effect with the prescribers." Id.

Forest Labs denies that Lexapro causes a new or increased risk of suicide in adults,[3] asserts that it did in fact convey the March FDA Public Health Advisory to doctors, and argues that both Drs. Andres and Doyle were independently aware of the risks as to which Higgins claims Forest Labs should have warned. As such, Forest Labs has asserted a number of substantive and procedural defenses.

II.

This matter has taken several years and a rather circuitous path to reach its present procedural posture. Higgins originally filed suit on July 18, 2006, as part of Multi-District Litigation ("MDL") 1736 in the Eastern District of Missouri. The MDL court transferred the matter here on

[2] The MDL court heard and rejected Forest Labs' motion to exclude Dr. Harrell's testimony on this point. In re Celexa & Lexapro Products Liab. Litig., No. MDL 1736, 2013 WL 791784, at *5 (E.D. Mo. Mar. 4, 2013).

[3] The current FDA approved warning for SSRIs and suicidality was first proposed in 2007. See FDA May 2, 2007 News Release, Dkt. No. 90-36, at 2. That warning updated the "black box" for SSRI medications "to include warnings about . . . suicidality[] in young adults ages 18 to 24 during initial treatment," but also "language stating that scientific data did not show this increased risk in adults older than 24, and that adults ages 65 and older taking antidepressants have a decreased risk of suicidality." Id. The current warning statement also "emphasize[s] that depression and certain other serious psychiatric disorders are themselves the most important causes of suicide." Id. Krivicich was 60 years old when he took his own life.

March 29, 2007, but it was transferred back to the MDL on July 20, 2007. Dkt. No. 39. On July 26, 2013, the action was remanded back to this district along with an MDL pretrial order, Dkt. No. 41, and an order reopening the case was entered on August 26, 2013. Dkt. No. 42. This court heard oral argument on a number of motions on June 20, 2014. Dkt. No. 133. At the hearing, the court granted Higgins' motion to amend her complaint,[4] denied her motion to certify a question of state law to the Virginia Supreme Court, and took under advisement the four remaining motions: two summary judgment motions by Forest Labs and a Daubert motion from each party. The court also requested the full deposition transcripts of a number of expert and fact witnesses, including Drs. Andres and Doyle. Finally, because the court permitted Higgins' to amend her complaint, it gave leave for Forest Labs to file a responsive summary judgment motion within two weeks.

Forest Labs filed the instant motion for summary judgment on July 11, 2014. Dkt. No. 144. Forest Labs seeks summary judgment on both Higgins' negligence claim and breach of warranty claim on a number of grounds. Most notably Forest Labs argues it is shielded from liability under the learned intermediary doctrine because both Drs. Andres and Doyle were independently aware of the risks as to which Higgins claims Forest Labs should have warned. Higgins filed her response on July 17, 2014, Dkt. No. 149, and Forest Labs filed its reply on August 6, 2014. Dkt. No. 151. The court has carefully reviewed the entirety of the voluminous pleadings and evidence that have been submitted by the parties both before and after the hearing, and the matter is now ripe for adjudication.

[4] Specifically, the court found that while Higgins' complaint labeled her second count as "strict liability," which is not a cause of action recognized in Virginia, it nevertheless stated a claim for breach of an implied warranty of merchantability under Virginia law. The court therefore granted her leave to correct the complaint with the proper caption for that count. The court explained its reasoning for this ruling on the record at the June 20, 2014 hearing.

III.

Pursuant to Federal Rule of Civil Procedure 56(a), the court must "grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986); Glynn v. EDO Corp., 710 F.3d 209, 213 (4th Cir. 2013). When making this determination, the court should consider "the pleadings, depositions, answers to interrogatories, and admissions on file, together with . . . [any] affidavits" filed by the parties. Celotex, 477 U.S. at 322. Whether a fact is material depends on the relevant substantive law. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). "Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. Factual disputes that are irrelevant or unnecessary will not be counted." Id. (citation omitted). The moving party bears the initial burden of demonstrating the absence of a genuine issue of material fact. Celotex, 477 U.S. at 323. If that burden has been met, the non-moving party must then come forward and establish the specific material facts in dispute to survive summary judgment. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586–87 (1986).

In determining whether a genuine issue of material fact exists, the court views the facts and draws all reasonable inferences in the light most favorable to the non-moving party. Glynn, 710 F.3d at 213 (citing Bonds v. Leavitt, 629 F.3d 369, 380 (4th Cir. 2011)). Indeed, "[i]t is an 'axiom that in ruling on a motion for summary judgment, the evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in [her] favor.'" McAirlaids, Inc. v. Kimberly-Clark Corp., No. 13-2044, 2014 WL 2871492, at *1 (4th Cir. June 25, 2014) (internal alteration omitted) (citing Tolan v. Cotton, 134 S Ct. 1861, 1863 (2014) (per curiam)). Moreover, "[c]redibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge . . . ." Anderson, 477 U.S. at 255. However, the non-

moving party "must set forth specific facts that go beyond the 'mere existence of a scintilla of evidence.'" Glynn, 710 F.3d at 213 (quoting Anderson, 477 U.S. at 252). Instead, the non-moving party must show that "there is sufficient evidence favoring the non[-]moving party for a jury to return a verdict for that party." Res. Bankshares Corp. v. St. Paul Mercury Ins. Co., 407 F.3d 631, 635 (4th Cir. 2005) (quoting Anderson, 477 U.S. at 249). "In other words, to grant summary judgment the Court must determine that no reasonable jury could find for the non[-]moving party on the evidence before it." Moss v. Parks Corp., 985 F.2d 736, 738 (4th Cir. 1993) (citing Perini Corp. v. Perini Const., Inc., 915 F.2d 121, 124 (4th Cir. 1990)).

IV.

A.

"Under Virginia law . . . manufacturers and sellers of defective products can be held liable on theories of negligence and breach of the implied warranty of merchantability." Bly v. Otis Elevator Co., 713 F.2d 1040, 1042 (4th Cir. 1983) (citations omitted), on reh'g sub nom. Farish for Farish v. Courion Indus., Inc., 754 F.2d 1111 (4th Cir. 1985); see also Abbot by Abbot v. Am. Cyanamid Co., 844 F.2d 1108, 1114 (4th Cir. 1988) ("Under Virginia law, recoveries for personal injuries caused by defective products can be made as breach of an implied warranty of merchantability or under a tort theory of negligent design."). The elements of both a negligence and a warranty cause of action are largely identical.[5]

> Under either the warranty theory or the negligence theory the plaintiff must show, (1) that the goods were unreasonably dangerous either for the use to which they would ordinarily be put or for some other reasonably foreseeable purpose, and (2) that the unreasonably

[5] There are two primary differences between the two species of liability. First, a warranty claim "focuses on whether the inadequate warnings render the product unreasonably dangerous," while a negligence claim, by contrast, "looks at whether the manufacturer's conduct is unreasonable." Moyers v. Corometrics Med. Sys., Inc., 210 F.3d 361, 2000 WL 345399, at *5 n.6 (4th Cir. 2000) (unpublished per curiam table decision). Second, a negligence claim is unique in that "the duty to warn is continuous and is not interrupted by manufacture or sale of the product." Id.

> dangerous condition existed when the goods left the defendant's hands.

Logan v. Montgomery Ward & Co., Inc., 216 Va. 425, 428, 219 S.E.2d 685, 687 (1975) (citations omitted). "Unreasonably dangerous" products include products that are not accompanied by adequate warnings about their hazardous properties. Butler v. Navistar Int'l Transp. Corp., 809 F. Supp. 1202, 1206 (W.D. Va. 1991) (collecting cases); see also Abbot, 844 F.2d at 1114 (same). Here, Higgins asserts under both her negligence claim and her breach of warranty claim that Forest Labs failed to provide an adequate warning about the hazardous properties of Lexapro. One of the many defenses asserted by Forest Labs is that it is shielded from liability by the learned intermediary doctrine.

1.

Generally, a manufacturer has a duty to warn its customers of risks posed by its products. In re Zyprexa Products Liab. Litig., No. 04-MD-1596, 2009 WL 2487305, at *12 (E.D.N.Y. July 27, 2009)(citing Stanback v. Parke, Davis & Co., 657 F.2d 642, 644 n.2 (4th Cir. 1981)). Where there is a genuine issue regarding the adequacy of the warning, summary judgment on a failure to warn claim is improper. Abbot, 844 F.2d at 1115 (citing Pfizer, Inc. v. Jones, 221 Va. 681, 683-84, 272 S.E.2d 43, 44-45 (1980)). However, the learned intermediary doctrine provides a limited exception to this general rule. Talley v. Danek Med., Inc., 179 F.3d 154, 162 (4th Cir. 1999) (citing Reyes v. Wyeth Lab., 498 F.2d 1264, 1276 (5th Cir. 1974)). Specifically,

> [t]he "learned intermediary" doctrine provides that manufacturers of prescription drugs and medical devices discharge their duty of care to patients by providing adequate warnings to the prescribing physicians.

In re Zyprexa, 2009 WL 2487305, at *12 (citing Restatement (Third) of Torts: Products Liability § 6 cmt. d, reporters' note (1997); Talley, 179 F.3d at 162). Critically, "[e]ven if a drug warning was deficient, a manufacturer is not liable when the prescribing physician was independently aware of the

risks that should have been communicated by the manufacturer and chose to administer the drug anyway." In re Zyprexa, 2009 WL 2487305, at *13 (citing Stanback, 657 F.2d at 645); see also Talley v. Danek Med., Inc., 7 F. Supp. 2d 725, 730 (E.D. Va. 1998) (citing Stanback, 657 F.2d at 645) ("Even if the manufacturer provides inadequate information, however, the manufacturer will not be liable if the plaintiff's physician independently knew of the risks and failed to advise the plaintiff."), aff'd, 179 F.3d 154 (4th Cir. 1999). Indeed, "a plaintiff must not only show that a manufacturer's warning was inadequate, but that such inadequacy affected the prescribing physician's use of the product and thereby injured the plaintiff." Talley, 7 F. Supp. 2d at 730.

2.

In 1980, the Supreme Court of Virginia called it "an elementary principle of law" that "in the case of prescription drugs, it is the general rule that the duty of the drug manufacturer is to warn the physician who prescribes the drug in question[.]" Pfizer, 221 Va. at 684, 272 S.E.2d at 44 (internal quotation omitted). A year later, the Fourth Circuit in Stanback v. Parke, Davis & Co., observed that "the well-settled rule is that the duty an ethical [i.e., a prescription] drug manufacturer owes to the consumer is to warn only physicians (or other medical personnel permitted by state law to prescribe drugs) of any risks or contraindications associated with that drug." 657 F.2d at 644 (collecting cases). Although the Fourth Circuit did not find a Virginia case on point, it "assume[d] that the Virginia Supreme Court would follow the general rule." Id.

In Stanback, a plaintiff contracted Guillain-Barre Syndrome ("GBS") after receiving a dose of the flu vaccine, Fluogen. Id. at 643-44. The package insert for Fluogen did not warn of the risk of contracting GBS. Id. at 644. The doctor who administered the vaccine testified that he did not read the Fluogen package insert, but he was aware of the risk of GBS associated with the vaccine. Id. The doctor did not advise patients about the risk of GBS either. Id. at 645. The Fourth Circuit determined that even if the manufacturer of Fluogen had adequately warned the administering

doctor in that case, the "uncontradicted evidence establishe[d] that [the plaintiff] would have nevertheless received the flu vaccinations despite the slight risk, and would not have been informed of the risk." Id. at 645. Because the doctor was fully aware of the "information which an adequate warning would have contained" the manufacturer of Fluogen was not liable for its failure to warn. Id. The district court's granting of summary judgment in favor of the manufacturer was proper because the plaintiff "failed to adduce sufficient proof of causation under any of the theories of liability set forth in her complaint." Id. at 646.

In Barnette v. E.R. Squibb & Sons, Inc., 670 F. Supp. 650 (E.D. Va. 1987), the court cited the district court decision in Stanback and the Supreme Court of Virginia's decision in Pfizer in observing that "the parties were in agreement that, under Virginia law, the manufacturer of a prescription drug has a duty to warn the physician or medical profession of its potential side effects, but that this duty does not extend to the patient." Id. at 651 (citing Stanback v. Parke, Davis & Co., 502 F. Supp. 767, 770 (W.D. Va. 1980), aff'd, 657 F.2d 642 (4th Cir. 1981); Pfizer, 221 Va. at 684, 272 S.E.2d at 44-45)). Similarly, the Fourth Circuit cited its previous decision in Stanback as well as the Pfizer case in Abbot, when it observed as follows: "With prescription drugs, the duty is not the normal duty to warn the ultimate consumer. Rather, the duty is to warn the physician administering the drug." 844 F.2d at 1115 (citing Stanback, 657 F.2d at 644; Pfizer, 221 Va. at 684, 272 S.E.2d at 44).

The Fourth Circuit addressed the learned intermediary doctrine under Virginia law twice more in the 1990s. In Kling v. Key Pharmaceuticals, Inc., 35 F.3d 556, 1994 WL 477815 (4th Cir. 1994) (unpublished per curiam table decision), the Fourth Circuit found that "[u]nder *well-established Virginia law*, a prescription drug manufacturer owes the consumer the duty of warning only the consumer's physician, or other person authorized to prescribe drugs, of risks or contra-indications associated with a drug." Id. at *2 (emphasis added) (citing Stanback, 657 F.2d 642). In Kling, a

plaintiff suffered a seizure that left him permanently disabled after taking a drug to treat his asthma. Id. at *1. The sudden onset of seizures was a well-known side effect of the drug and documented in the Physician's Desk Reference and in the drug's package inserts. Id. The prescribing doctor testified that stricter warnings would not have affected his decision to prescribe the drug. Id. at *2. The district court granted the manufacturer's Rule 50 motion, and the Fourth Circuit affirmed because seizures were well known side effects, and the plaintiff failed to prove causation in light of the doctor's testimony that stronger warnings would not have altered his decision to prescribe the drug. Id. at *2-3.

The Fourth Circuit again addressed the doctrine in Talley v. Danek Medical, Inc., 179 F.3d 154 (4th Cir. 1999). In Talley, the district court concluded that the plaintiff was essentially bringing failure to warn claims and held that under Virginia's learned intermediary doctrine the defendant need only warn physicians and not their patients. Id. at 162 (citing Abbot, 844 F.2d at 1115). On review, the Fourth Circuit held that "the district court correctly applied the learned intermediary doctrine." Id. at 164. In that case, a doctor had a consulting relationship with a medical device manufacturer. Id. The plaintiff failed to show causation where the doctor testified that he did not always choose that manufacturer's device but used his independent medical judgment based on the circumstances of each patient and sometimes used competitor's similar devices. Id. at 163-64.

More recently, a number of Virginia trial courts and federal district courts sitting in diversity have continued to recognize the viability of the learned intermediary doctrine under Virginia law. In Hamlett v. Virginia Vascular Associates, 61 Va. Cir. 468, 2003 WL 22382792 (Norfolk Cir. Ct. Apr. 21, 2003), the court, citing Pfizer, observed that "[a]lthough no Virginia case mentions the 'learned intermediary doctrine,' the Supreme Court of Virginia has applied the doctrine to a manufacturer of prescription drugs." Hamlett, 2003 WL 22382792, at *4 (citing Pfizer, 221 Va. at 684, 272 S.E.2d at 44). In Wright v. Lilly, 66 Va. Cir. 195, 2004 WL 2656839 (Portsmouth Cir. Ct. Nov. 15, 2004), the

court, citing both Pfizer and Hamlett, noted that "successful assertion of the learned intermediary defense might be a complete bar to liability against the pharmaceutical manufacturers." Wright, 2004 WL 2656839, at *14 (citing Pfizer, 221 Va. at 684, 272 S.E.2d at 44; Hamlett, 2003 WL 22382792, at *4).

The doctrine was also applied in Evans v. Mentor Corp., No. CIV.A. 1:04CV1218, 2005 WL 1667661 (E.D. Va. June 28, 2005), where the United States District Court for the Eastern District of Virginia, sitting in diversity, held that the

> [p]laintiff's failure to warn claim is barred by the learned intermediary doctrine. That doctrine provides that "manufacturers of prescription medical products have a duty only to warn physicians, rather than patients, of the risks associated with the use of the product." Talley, 7 F. Supp. 2d at 730; see also Pfizer, 221 Va. 681, 272 S.E.2d 43. The doctrine applies in "circumstances where (1) ethical drugs or medical devices that can be prescribed or installed only by a physician are involved and (2) a physician prescribes the drug or installs the medical device after having evaluated the patient." Talley, 179 F.3d at 163.

Id. at *3 (full cites omitted). In Hart v. Savage, No. L-04-1663, 2006 WL 3021110 (Norfolk Cir. Ct. Oct. 19, 2006), yet another Virginia trial court observed that that "the Supreme Court of Virginia has never explicitly adopted" the learned intermediary doctrine, but that "it seems to have approved it with regard to prescription drugs in Pfizer" and that the Fourth Circuit, applying Virginia law, had applied the doctrine in Talley. Id. at *2.

Finally, the United States District Court for the Eastern District of New York applied Virginia law in In re Zyprexa Products Liability Litigation, No. 04-MD-1596, 2009 WL 2487305 (E.D.N.Y. July 27, 2009), and undertook an extensive survey of Virginia law on the learned intermediary doctrine. It concluded that "[t]he concept of the learned intermediary doctrine has been recognized by the Virginia Supreme Court and regularly applied by the state's courts." Id. at *12 (citing Pfizer, 221 Va. at 684, 272 S.E.2d at 44; Talley, 179 F.3d at 162-63; Hart, 2006 WL

3021110, at *2; Hamlett, 2003 WL 22382792, at *4). In re Zyprexa is yet another example where the court ruled that even if the manufacturer's warning for a prescription drug was inadequate, the evidence of the prescribing physician's knowledge of the drug's risks "constitute[d] an intervening act that [broke] the chain of causation . . . ." Id. at *14-15.

In light of all these authorities, it is plain that the learned intermediary doctrine has been and remains a part of Virginia law. Although Pfizer never employs the term "learned intermediary doctrine," it clearly applied the doctrine, and in the context of a prescription drug failure to warn case no less. Numerous holdings, including multiple decisions by the Fourth Circuit Court of Appeals, have invoked the doctrine when applying Virginia law in reliance on Pfizer. There is no doubt of its applicability here.

As the depositions of treating psychiatrists Drs. Andres and Doyle make clear, Krivicich's treating psychiatrists were well aware of the risks of prescribing SSRIs such as Lexapro when they treated him in 2004. As such, there is no basis to impose liability on the drug manufacturer for allegedly failing to warn a treating physician of risks associated with a medication as to which the physician is already aware.[6]

B.

In considering this case, it is helpful to outline Krivicich's treatment with Drs. Andres and Doyle in the six months before his suicide.

Dr. Andres first saw Krivicich on February 7, 2004, and evaluated him for more than one hour. Andres Dep., Dkt. No. 152, at 58-59. During that visit, Krivicich reported experiencing

[6] It is worth noting that Forest Labs contends that the labels accompanying Lexapro were in accordance with FDA requirements and that its label was changed consistent with the March 2004 FDA Public Health Advisory. Forest Labs further maintains that it provided revised package inserts to Krivicich's psychiatrists before he was last seen by them. Accordingly, Forest Labs contends that Higgins' claims are preempted by federal law and that its warnings were adequate. Because the court concludes that the evidence is undisputed that Krivicich's treating psychiatrists were independently aware of the risks associated with prescribing SSRIs such as Lexapro while they were treating Krivicich, the court need not reach these issues.

stress, anxiety, tension, low energy and motivation, insomnia, and decreased mood. Id. at 67. Krivicich acknowledged having fleeting thoughts of suicide. Id. at 68. Dr. Andres prescribed Remeron, a "serotonin-related" antidepressant, focusing first on Krivicich's "horrible problems with sleep." Id. at 69-70. Krivicich missed his next appointment with Dr. Andres, scheduled for February 14, 2004, and rescheduled for February 28, 2004. On that date, Krivicich indicated that he remained anxious but had stopped taking the Remeron because it made him too sleepy. Dr. Andres started Krivicich on five milligrams of Lexapro for one week, with instructions to increase the dosage to ten milligrams thereafter, along with Trazodone and Ativan at bedtime. Id. at 71-72. Dr. Andres next saw Krivicich on March 20, 2004, at which time Dr. Andres continued the ten milligrams of Lexapro along with Klonopin, a quick acting benzodiazepine anti-anxiety medication, which was prescribed to help reduce Krivicich's anxiety at night. Id. at 77-79. During his next visit, a month later on April 17, 2004, Krivicich reported that he had stopped taking Lexapro after one month due to unspecified side effects. Id. at 81. At the April 17 visit, Dr. Andres prescribed another antidepressant, Zoloft. Id. at 82. At the next visit, on May 22, 2004, Krivicich reported that he had discontinued use of the Zoloft because it interfered with his concentration. Id. at 85. Krivicich did not appear for his next scheduled appointment with Dr. Andres, so Dr. Andres called him on May 29, 2004. At that time, Krivicich reported that he had taken himself off of all medications but was having trouble sleeping, only one to two hours per night. Id. at 89.

Dr. Andres' last visit with Krivicich was on July 10, 2004. That visit was precipitated by calls to Dr. Andres from Krivicich's friends who were concerned that he was suicidal. Id. at 93. Krivicich reported that he had recently begun taking five milligrams of Lexapro because it helped with his sleep. Krivicich told Dr. Andres that "he was not suicidal, had no intention or plan, and that he would not do that because of his family." Id. at 96-97. Dr. Andres gave Krivicich a prescription for ten milligrams of Lexapro. Dr. Andres' notes from that visit reflect that Krivicich

did not intend on coming back to see Dr. Andres, and Dr. Andres advised Krivicich to follow up with him or his primary care physician to manage his medications. Id. at 97.

Krivicich saw Dr. Brian Doyle, also a board certified psychiatrist, six days later, on July 16, 2004. Doyle Dep., Dkt. No. 153, at 44. A concerned neighbor brought Krivicich to see Dr. Doyle, who found Krivicich to be severely depressed. Id. at 53. Dr. Doyle's treatment notes indicated that Krivicich told him that he was anxious and felt overwhelmed, helpless, and hopeless. Id. at 47. He told Dr. Doyle that "maybe everyone would be better off without me," which Dr. Doyle testified was a common indicator of someone who at least has suicidal ideation. Id. at 49. At the same time, Dr. Doyle did not consider Krivicich to be acutely dangerously suicidal. Id. at 96-97.[7] Dr. Doyle agreed with the prescription of Lexapro and Klonopin. Id. at 65. Dr. Doyle testified that he did not think that Krivicich had taken his antidepressant medications for a sufficient period of time or in a sufficient dosage to see the benefit of the medicines. Id. at 81.[8] As Dr. Doyle explained, SSRIs such as Lexapro, while effective at treating anxiety, do not act right away. Klonopin, a benzodiazepine, acts within hours, and is designed to provide short term anxiety relief. Id. at 65-66.

Dr. Doyle explained that in 2004, when he saw Krivicich, it was his standard practice to discuss the pros and cons of the medications, including the following:

> I would usually say there are some people who do worse when we try them on this medication, either feeling more depressed or more anxious or both, that there is some risk in the literature of patients committing suicide, although that has not been my experience in my

[7] Dr. Doyle testified that had he thought that Krivicich was acutely, severely suicidal, he would have called his wife right away and taken steps to have him promptly evaluated in a more secure environment. Doyle Dep., Dkt. No. 153, at 96. In hindsight, Dr. Doyle testified that "I think I should have contacted Kathleen [Higgins]." Id. at 117. But Dr. Doyle did not testify that this was due to a lack of knowledge on his part about the propensities of the medications he was prescribing. Rather, he testified that "[t]here's a larger umbrella here for reasons that I should have called Kathleen." Id. at 118.

[8] Dr. Doyle testified that the minimal therapeutic dose of Lexapro is ten milligrams and that it is generally regarded that the natural course of response to the medication is to be on a therapeutic dose for three to four weeks. Doyle Dep., Dkt. No. 153, at 81.

> clinical practice. It is in the literature and so you need to be aware of it.

Id. at 82-84. Dr. Doyle testified that he was impressed with the burden of Krivicich's symptoms, both the severity of his depression and the intensity of his anxiety, such that he asked permission to speak with his psychiatrist. Id. at 87-88. Although Krivicich did not give Dr. Doyle permission to speak with his treating psychiatrist, Dr. Doyle believed Krivicich would recontact his treating psychiatrist. Id. at 64, 87-90. Instead, nine days later, on July 25, 2004, Krivicich committed suicide.

C.

In this failure to warn case, Higgins must prove that Forest Labs failed to warn Drs. Andres and Doyle about the risk of new or increased risk of suicidality with Lexapro treatment. As detailed in their depositions, however, both Drs. Andres and Doyle were independently aware of this risk at the time they prescribed Lexapro in their treatment of Krivicich. As both treating doctors were fully cognizant of the ongoing scientific debate concerning the risk of prescribing SSRIs such as Lexapro, there can be no actionable failure to warn claim.

Dr. Andres testified at his deposition about his awareness of a potential link between SSRIs and suicidality at the time he treated Krivicich.

> Q: Dr. Andres, going back to 2004, specifically the period of time when you treated Francis Krivicich, were you aware of a debate, a scientific debate or debate within the medical community, about the possible link between the use of SSRI medications and emerging suicidal thinking?
>
> A: Yes.
>
> Q: Can you tell me what you understood of that – that debate, that issue, in 2004?
>
> A: Well, it became a – something of that was well known to the public. And the – debate was – among the psychiatrists was ongoing. And some people were saying that it was a major problem, other people were not, but it was an issue. It was in the minds of people.

These – in the department of psychiatry, we have case conference meetings and professional meetings that are held. And that – that was an issue that would come up at times. The – the end product of all of that was that it was – even today it would be considered an issue in the younger population. So you become a little more – in that group, a little more sensitive to the issue.

The latest kind of thinking is that the probability of suicide is less if you give the medication, because of the antidepressant effect. So it moves in the direction which is saying you should give the medications even to young people and then just be aware of the possibility.

With – in the specific case with Mr. Krivicich, the – I can't remember exactly the context where that came up. But my hunch is – and I – and that the family was aware of the debate and that that ended – and that it influenced the conversation that he had with his family. So it – it was an issue. My hunch is – I can't remember exactly what was said. My hunch is the issue came up in that context and then he decided to continue with it at least for a while.

Q: Doctor, the issue that we're discussing, the ongoing debate about whether the SSRIs themselves could cause suicidal thinking or suicide, were you aware of that debate prior to 2004, prior to your treatment of Francis Krivicich?

A: I – I'm not sure of the – if it was in the – in the public arena; it was in the private arena I'm sure because we saw a ton of people who were depressed . . . . That was the main diagnosis. . . . I can't imagine not having that kind of knowledge at issue.

Q: And to follow up on an answer you just provided, if I understand what you're saying, if there was information in the media, information in the scientific community, about the possible link between these two, you would have been aware of it when that became public?

* * *

A: Yes.

Andres Dep., Dkt. No. 152, at 24-27.

In his deposition, Dr. Andres explained his knowledge of the health concerns concerning antidepressant medications and suicidability reflected in the substance of the Lexapro package insert

following the FDA's March, 2004 Public Health Advisory. Id. at 31-34. As his testimony makes clear, Dr. Andres was fully aware at the time he was treating Krivicich that patients with major depressive disorders may experience worsening of their condition whether or not they are on medication; that there was a long-standing concern that antidepressants may have a role in inducing worsening of depression and emergence of suicidality in certain patients; and that patients being treated with antidepressants should be closely observed for worsening of their symptoms and the emergence of suicidality. Id. at 31-34. Dr. Andres' testimony makes it very clear that, while not expressly addressing the issue with Krivicich when he prescribed Lexapro, he was well aware of the issue of whether SSRIs themselves could have a link to emerging suicidality. Id. at 74-76. Dr. Andres testified that even given a warning "that the use of Lexapro itself could cause [Krivicich] to commit suicide," he "would have prescribed Lexapro. [He] had a lot of experience with it, and that influences the choice." Id. at 133-34. Even considering the current FDA approved label containing a "black box" warning for suicidality for young adults under age 25, Dr. Andres would have prescribed Lexapro for Krivicich.

> Q. Okay. So, again, would this have changed in any way – this warning, this black box warning, change in any way your decision to prescribe Lexapro to Mr. Krivicich, who was 60 at the time you treated him?
>
> A. No. I mean I would feel free to use it.

Id. at 148-49. As Dr. Andres explained, both in 2004 and today, the central concern is that the underlying depression itself causes an increased risk of suicide and that central issue needs to be developed and pursued. Both in 2004 and today, Dr. Andres would speak to such patients about concerns of worsening of their symptoms or of the development of suicidal thinking. Id. at 148-51.

Dr. Doyle, who saw Krivicich shortly before his death, testified consistently.

> Q: Doctor, at the time that you treated Mr. Krivicich in 2004, from that point in time forward, were you aware that there was a debate

within the scientific and medical community as to whether SSRI medications could be causally linked to suicide or suicidal thinking?

A: Yes.

Doyle Dep., Dkt. No. 153, at 24. Doyle clarified this testimony later in deposition:

Q: And the main thing is I'm trying to determine whether you were aware of this concern, this ongoing debate, at the time prior to treating Mr. Krivicich in 2004.

A: Yes.

Q. Okay. Now, if you can, during that period, the '90s and early 2000s, what was your understanding of the debate at that time? And I appreciate you can't identify it to a specific day.

A. The debate was whether the medications gave – caused patients to have de novo psychiatric ideation or worsened psychiatric ideation or whether this was simply suicidal ideation in a patient who is already severely depressed and might be having suicidal ideation anyway, regardless of whether or not he or she was taking medicine.

* * *

Q. Now, when you did become aware of the debate about the possible link between SSRI medications and depression – and if I understand, you were aware of that before you treated Mr. Krivicich?

A. Yes.

Q. Is that something that you took into consideration when you were treating patients that had depression or anxiety and for whom you may have considered prescribing antidepressants, SSRIs?

A. Yes.

Q. And how did you factor that – the debate, the discussion, into your treatment plan, if you will?

A. Again, it's difficult to do it around a specific time, but I suspect by the time my clinical stance was that many more lives were saved by the antidepressants and their appropriate use than were lost as a result of using the SSRIs. So even if the assertions that these medications might lead to suicidal behavior or make it worse were true and that some patients were lost as a result of that, the overall benefit was massively on the side of using the antidepressants for patients who are depressed.

Id. at 26-28.

As did Dr. Andres, Dr. Doyle plainly testified that he knew of the substance of the March 2004 FDA Advisory regarding SSRIs when he treated Krivicich in 2004.

> Q. And, Doctor, regarding the first – the first statement, that "Patients with major depressive disorder . . . may experience worsening of their depression and/or the emergence of suicidal ideation . . . whether or not they are taking antidepressants," in 2004, when you treated Mr. Krivicich, was that consistent with your treatment practice or your understanding?
>
> A. Yes.
>
> Q. I mean I guess a better question is: Do you agree with that?
>
> A. Yes. I mean – I mean yes, patients with – with depression may become suicidal at any point in their careers independent of taking antidepressant medication. Yes.
>
> Q. The next full sentence, the one that reads "Although there has been a long-standing concern that antidepressants may have a role in inducing worsening of depression and the emergence of suicidality in certain patients, a causal role for antidepressants in inducing such behaviors has not been established," that appears to be consistent with your testimony of your understanding of the discussion or the debate in 2004. Is that correct?
>
> A. That's correct.
>
> Q. So I mean do you – as of 2004, when you treated Francis Krivicich, is the sentence that I just read consistent with your belief at that time?
>
> A. Yes.
>
> Q. The next sentence reads, I guess, to paraphrase, that whether or not there's a causal role, that nevertheless, that patients being treated with antidepressants, especially at the beginning of drug therapy, should be watched closely for worsening of their symptoms or the emergence of suicidal thinking.
>
> A. That's correct.
>
> Q. Was that consistent with your treatment practice in 2004?

A. Yes.

* * *

Q. Did you advise your patients that they should be watchful for a worsening of their symptoms or the emergence of suicidal thinking?

A. I routinely told patients then, as now, that a worsening of depressive symptoms, including suicidal impulses, could occur and those should be reported to me immediately.

Id. at 31-33.

On cross-examination, Dr. Doyle was asked about efforts by Forest Labs to bring the March 2004 FDA Public Health Advisory to his attention.

Q. Do you have any recollection between March of '04 and the time that you treated Francis in July of any Forest sales representative bringing your attention to this March '04 FDA advisory with respect to SSRI medications and the increase in suicidality in patients taking them?

A. I don't remember their referencing it, but my clinical literature was full of it. This was a very hot topic. So I mean I was getting information from that. I don't remember if Forest told me about that.

Q. Okay. Do you recall if this literature that you just referenced was calling your attention to this between March and July of that year or was it after that? That's what I'm trying to filter out.

A. My literature had been full of this controversy for the last couple of years before this.

Q. Before '04?

A. Yeah. I mean this was not – this was not new. I mean this was – I mean the point about this was that, you know, this controversy had been boiling along and then the FDA issued this warning and then gave the black box deal, which had a big impact on us as clinicians. So this was very hot.

Id. at 108-09. In Dr. Doyle's words, "So, you know, we're already on board about all this stuff. It doesn't have to do with whether or not the pharmaceutical reps are talking to us about it." Id. at 113.[9]

On redirect, Dr. Doyle confirmed that he knew of a new or increased risk of suicide from SSRIs prior to treating Krivicich.

> Q: Did – prior to treating Francis Krivicich –
>
> A: Yes.
>
> Q: – did either the literature or any sales representative or Dear Doctor letter from Forest Laboratories ever convey the message to you that the use of this medication can cause de novo suicidality or worsening of suicidality?
>
> * * *
>
> A: Yes.
>
> Q: Okay. What conveyed that to you?
>
> A: It's hard for me to specify where that information came from, but my clinical literature from the journals and the newsletters was – was all congruent around this issue. So there was abundant information to me from more than one source.

Id. at 127. In the final question asked at the deposition by counsel for Higgins, Dr. Doyle reiterated:

[9] Given the entirety of Dr. Doyle's testimony, the court does not read his testimony at pages 121 and 122 of his deposition as creating a genuine issue of material fact. In this portion of his testimony, Dr. Doyle explained that certain information on SSRIs has surfaced since 2004. Namely, he indicated that he was not aware in 2004 that there are certain small subpopulations of patients for which SSRI medications cause an increase in suicidality. Doyle Dep., Dkt. No. 153, at 121. Importantly, he immediately clarified "that the group that you're most worried about are the adolescents, that they seem to be particularly prone to be tipped towards suicidal thinking or having suicidal thinking worse by taking the SSRIs. . . . [I]n clinical fact, it's the adolescents who are at increased risk." Id. at 121-22. While Dr. Doyle agreed that it was possible that Krivicich was in "that small subpopulation of patients where these medications just don't agree," id. at 122, that possibility does not negate Dr. Doyle's clearly expressed testimony as to the state of his knowledge at the time he was treating Krivicich of the risks of suicidality associated with treatment using SSRIs such as Lexapro. As such, the court does not believe that this testimony creates a genuine issue of material fact for the jury as to Forest Labs' duty to warn Dr. Doyle as to what he already knew.

> Q: And it's your testimony that that article or something similar to that, prior to treating Francis, conveyed the message the medications do cause this, not can but do?
>
> A: Yes.

Id. at 129.

Thus, there is no genuine dispute of material fact regarding the knowledge possessed by either doctor when they were treating Krivicich in 2004. Both Drs. Andres and Doyle testified that they were aware, prior to treating Krivicich, that SSRIs, while generally effective in treating anxiety and depression, could cause an increased risk of suicidality in certain patients, and that, as such, patients should be closely monitored. Both doctors testified that it was their standard practice to instruct the patient to be on the lookout for increased anxiety or depression. As the testimony of Krivicich's treating psychiatrists clearly establishes that they were independently aware of the risks Higgins claims Forest Labs should have warned, there is no basis upon which any reasonable jury could impose failure to warn liability on Forest Labs under either a negligence or warranty theory. In short, because Kricivich's treating psychiatrists were well aware of the risks associated with treating anxious and depressed patients with SSRIs in 2004, Higgins cannot show that Forest Labs' failure to warn was the cause in fact of Kricivich's suicide. Stanback, 657 F.2d at 647; In re Zyprexa, 2009 WL 2487305, at *14-15.

V.

The overarching background of this case obviously involves highly complex medical issues as well as a real human tragedy. Nevertheless, the outcome is ultimately determined by a relatively straightforward application of Virginia law. In light of the testimony of Drs. Andres and Doyle, and given the nature of the facts regarding the overwhelming abundance of information on the issue of SSRIs and the risk of suicidality of which they testified they were aware at the time they treated Krivicich, the court is constrained to conclude that there is no genuine issue of material fact in

dispute. Because Virginia law does not permit a drug manufacturer to be liable for failure to warn of a risk of which a treating physician was independently aware, and Krivicich's doctors plainly testified as to their awareness of the risk of increased suicidability associated with SSRIs, the court must award summary judgment in favor of Forest Labs. An appropriate Order will be entered this day.

The Clerk is directed to send a copy of this Memorandum Opinion to all counsel of record.

Entered: September 8, 2014

/s/ Michael F. Urbanski

Michael F. Urbanski
United States District Judge